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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/672,221	09/27/00	BOYLE B	HYS-26

HM12/0502

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EXAMINER	
SOUAYA, J	

ART UNIT	PAPER NUMBER
1655	5

DATE MAILED: 05/02/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/672,221	Applicant(s) Boyle et al
	Examiner Jehanne Souaya	Art Unit 1655

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on Sep 27, 2000 .

2a) ☐ This action is **FINAL.** 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 1-30 is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☐ Claim(s) _____ is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☒ Claims 1-30 are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)

16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____

18) ☐ Interview Summary (PTO-413) Paper No(s). _____

19) ☐ Notice of Informal Patent Application (PTO-152)

20) ☐ Other:

DETAILED ACTION

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-9, 14-16, 18-20, and 24, drawn to nucleic acids, vectors, host cells and nucleic acid based assays, classified in class 536, subclass 23.1; class 435, subclass 320.1; class 435, subclass 325, and class 435, subclass 6 respectively.

II. Claims 26-28, drawn to nucleic acid arrays, classified in class 435, subclass 6.

III. Claims 10-13, 21-23, and 25, drawn to polypeptides, classified in class 530, subclass 350.

IV. Claim 17, drawn to antibodies, classified in class 424, subclass 130.1.

V. Claims 29-30, drawn to methods of treating, classified in class 514, subclass 44.

2. The inventions are distinct, each from the other because of the following reasons: The inventions of Groups I and II are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because 1) the utility of a polynucleotide array does not necessarily depend on the utility of each separate

polynucleotide in the array, and 2) the polynucleotide array of Group II can be used in a method to identify differential expression of many different genes. The subcombination has separate utility such as the distinct polynucleotides of Group I can be used in recombinant methods to express proteins.

3. The inventions of groups I, III, and IV are patentably distinct because they are drawn to different products having different structures and functions. The nucleic acid of group I is composed of deoxyribonucleotides linked by phosphodiester bonds and assumes the form of a double helix. The polypeptide of group III is composed of amino acids linked by peptide bonds and can assume complex tertiary structures. While the antibody of group IV is also composed of amino acids linked by peptide bonds, antibodies are glycosylated and their tertiary structure is unique, where four subunits (2 light chains and 2 heavy chains) associate via disulfide bonds into a Y-shaped symmetric dimer. The products of groups I, III, IV can be used in materially different processes, for example the DNA of group I can be used in hybridization assays, the antibody of group IV can be used in immunoassays, and the polypeptide of group III can be used to make a fusion protein with an enzymatic function. Consequently, the reagents, reaction conditions, and reaction parameters required to make or use each invention are different. Therefore, the inventions of groups I, III, IV are patentably distinct from each other.

4. The inventions of Group II and the inventions of Groups III, IV, and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP

§ 806.04, MPEP § 808.01). In the instant case the different inventions have different structures, different effects and are not capable of use together.

5. The invention of Group V is patentable distinct from the inventions of Groups I, III, and IV because the method of treatment of Group V is unobvious over the products of Groups I, III, and IV. The inventions require different reagents, reaction conditions and reaction parameters.

6. Additionally, applicant is required to elect patentably distinct nucleic acid sequences. This is NOT an election of species. For example, the polypeptide of SEQ ID NO 4 is encoded by the polynucleotide of SEQ ID NO 3. Additionally, the polypeptide sequences of SEQ ID NOS 6-16, represent fragments of SEQ ID NO 4, therefore, the sequences of SEQ ID NOS 3, 4, and 6-16 belong to a single patentably distinct invention. It cannot be determined from the disclosure in the specification, how the sequences of SEQ ID NOS 2, 5, 17, and 18 are related to each other or to SEQ ID NOS 3, 4, and 6-16, therefore the sequences of SEQ ID NOS 2, 5, 17, and 18 appear to be drawn to patentably distinct inventions. By statute, "[i]f two or more independent and distinct inventions are claimed in one application, the Commissioner may require the application to be restricted to one of the inventions." 35 U.S.C. 121. Pursuant to this statute, the rules provide that "[i]f two or more independent and distinct inventions are claimed in a single application, the examiner in his action shall require the applicant... to elect that invention to which his claim shall be restricted." 37 CFR 1.142 (a). See also 37 CFR 1.141(a). Applicant is required to further elect the invention of SEQ ID NOS 3, 4, and 6-16, or SEQ ID NO 2, or SEQ ID NO 5, or SEQ ID NO 17, or SEQ ID NO 18.

Nucleotide sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide sequences are presumed to represent an independent and distinct invention, subject to restriction requirement pursuant to 35 USC 121 and 37 CFR 1.141.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

7. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

8. Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group II-V, restriction for examination purposes as indicated is proper.

9. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

10. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

11. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jehanne Souaya whose telephone number is (703)308-6565. The examiner can normally be reached Monday-Thursday from 7:30 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152. The fax phone number for this Group is (703) 305-3014.

Any inquiry of a general nature should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Jehanne Souaya

Jehanne Souaya
Patent examiner
April 27, 2001

W. Gary Jones
Supervisory Patent Examiner
Technology Center 1600
5/1/01